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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,655	08/05/2003	Randall Lashinski	MITRAL.001CP3	6367

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

3P

<b>Office Action Summary</b>	Application No. 10/634,655	Applicant(s) LASHINSKI ET AL.	
	Examiner Urmi Chattopadhyay	Art Unit 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 24-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/3/03; 5/20/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-23 in the reply filed on 11/9/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 24-45 have been withdrawn from further consideration.

### ***Response to Amendment***

2. The preliminary amendment filed 5/20/04 has been entered. The change to the specification has been approved by the examiner.

### ***Priority***

3. The examiner has reviewed each of the priority applications, which are 10/066,302, 09/774,869 (USPN 6,537,314), 09/968,272 (6,709,456), 09/494,233 (6,402,781), 60/265,995, 60/429,281 and 60/488,334. Claims 1 and 13 receive benefit of the filing date of 60/429,281, and therefore have an effective filing date of November 25, 2002.

### ***Specification***

4. The disclosure is objected to because of the following informalities: in [0086], it appears that "B" should be changed to --30B--. Appropriate correction is required.

Art Unit: 3738

***Claim Objections***

5. Claim 16 is objected to because of the following informalities: on line 1, it appears that "15;" should be changed to --15-- (delete the semicolon). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 6 recites the limitation "the implantation configuration" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It appears that "implantation" should be changed to --delivery--.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3, 5-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. (USPAP 2003/0130731 A1) in view of Adams et al. (USPAP 2003/0083538 A1).

Art Unit: 3738

Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1, but is silent to the second curve being concave in a second direction. See Figures 4h-4i and [0124]-[0125] for an elongate body (110h) having proximal and distal ends. The elongate body (110h) is movable from a first, flexible configuration (Figure 4h) for transluminal delivery to at least a portion of the coronary sinus to a second configuration (Figure 4i) for remodeling the mitral valve annulus. A forming element (90) is attached to the elongate body (110h) for manipulating the elongate body (110h) from the first delivery configuration to the second remodeling configuration. See [0124] for the elongated body (110h) having a final shape with an increased radius of curvature in some regions and a decreased radius of curvature in other regions, which includes a first curve concave in a first direction. Adams et al. teaches a device (50) having a “w” configuration implanted into the coronary sinus, wherein a force is applied to a discrete portion (23) of the atrial wall (21) of the coronary sinus (14) in order to reshape the mitral valve annulus for treating dilated cardiomyopathy. See Figure 3 and [0051]. It would have been obvious to one of ordinary skill in the art at the time of applicant’s invention to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of the device is of a “w”. The “w” configuration includes the first curve in the first direction, a second curve concave in a second direction and a third curve concave in the second direction (claim 2). This shape will apply a force to a discrete portion of the atrial wall of the coronary sinus to reshape the mitral valve annulus in treating dilated cardiomyopathy.

Art Unit: 3738

Claim 3, see Figures 4h-4i and [0124] for the body comprising several wedge-shaped segments (95) with holes therethrough, together forming a tube with a plurality of transverse slots therein.

Claims 5 and 6, see [0124] for the apparatus being movable from the delivery configuration to the remodeling configuration in response to movement of the forming element (90).

Claim 7, see Figures 4h-4i for at least a first portion of the forming element (90) extending within the body (110h) and a second portion extending outside the body (110h).

Claim 8, see [0124] for an anchor assembly for engaging a site within a vessel.

With respect to claim 9, Vidlund et al. does not expressly disclose the embodiment shown in Figures 4h-4i including an anchor in the form of a barb for piercing the wall of the vessel, as required by claim 9. Vidlund et al. does, however, disclose a body (110c) including barbs in the embodiment shown in Figure 4c in order to engage with the vessel wall for maintaining the position of the body (110c) within the vessel. See Figure 4c and [0119]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention make the distal anchor assembly of the embodiment shown in Figures 4h-4i in the form of a barb in order to pierce the vessel wall to maintain the position of the body (110h) within the vessel.

With respect to claims 11 and 12, Vidlund et al. does not expressly disclose that the apparatus has an axial length of no more than about 10 cm and a maximum cross sectional dimension of no more than about 10 mm, as required by claims 11 and 12, respectively. However, it appears in [0125] that the apparatus of Vidlund et al. is sized and shaped for implantation in the coronary sinus of the heart, which is the same location the apparatus of

Art Unit: 3738

applicant's invention is being implanted. Given the dimensions of a human coronary sinus, it is obvious that the apparatus of Vidlund et al. would meet the axial length and maximum cross sectional dimension requirements of claims 11 and 12 in order for it to fit and operate within the coronary sinus.

10. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. and Adams et al. as applied to claims 1 and 8 above, and further in view of Alferness et al. (USPAP 2003/0105520 A1).

Vidlund et al., as modified by Adams et al., discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1, but is silent to the apparatus further comprising a lock for retaining the body in the second configuration, as required by claim 4. See [0124] for the forming element (90) being attached to an anchor assembly provided on the distal end of body (110h). Alferness et al. teaches a device (30) implanted in the coronary sinus, wherein a lock (44) on a distal anchor (36) locks the distal anchor (36) to a cable (42) in order to be able to adjust the amount of tension in the cable (42) to achieve a device configuration that provides the desired mitral valve geometry. See Figure 5 and [0021], [0035] and [0036]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Alferness et al. to modify the apparatus of Vidlund et al. by further including a lock on the anchor assembly for locking the forming element (90) to the anchor assembly in order to adjust and maintain the body (110h) in the second configuration.

Art Unit: 3738

Vidlund et al. and Adams et al. are also silent to the apparatus further comprising a first tissue anchor at the proximal end of the body, as required by claim 10. See [0124] for a second tissue anchor assembly at the distal end of the body (110h). Alferness et al. teaches the device (30) including a proximal anchor (36) and a distal anchor (32) in order to fix the device within the coronary sinus so that the configuration of the device can be changed to effect mitral valve geometry. See [0014] and Figure 3. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Alferness et al. to modify the apparatus of Vidlund et al. by including a first tissue anchor at the proximal end of the body (110h) in order to fix the body (110h) within the coronary sinus so that the configuration of the body (110h) can be changed to effect mitral valve geometry.

11. Claims 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. in view of Adams et al. and Alferness et al. (USPAP 2002/0169504 A1).

Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 13, but is silent to manipulation of the forming element deflecting the central section laterally with respect to at least a portion of the proximal and distal sections. See rejection of claim 1, supra. Adams et al. teaches a device (50) having a "w" configuration implanted into the coronary sinus, wherein a force is applied to a discrete portion (23) of the atrial wall (21) of the coronary sinus (14) in order to reshape the mitral valve annulus for treating dilated cardiomyopathy. See Figure 3 and [0051]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of



Art Unit: 3738

the device is of a “w”. The “w” configuration would be achieved by manipulating the forming element (90) to deflect the central section laterally with respect to the distal and proximal section, and includes a first curve in a first direction and a second curve concave in a second direction (claims 22 and 23). This shape will apply a force to a discrete portion of the atrial wall of the coronary sinus to reshape the mitral valve annulus in treating dilated cardiomyopathy.

Vidlund et al. is also silent to a detachable coupling on the body for removably attaching the body to a deployment catheter, as further required by claim 13. See [0125] for the body (110h) being implanted using a catheter. Alferness et al. teaches a mitral valve therapy device (30) that has a detachable coupling (46) on the proximal portion (44) of the device in order to removably attach with an introducer (56) that is used for positioning the device (30) in the coronary sinus. See [0050], [0054] and Figures 2 and 3. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings Alferness et al. to modify the implant of Vidlund et al. by including a detachable coupling on the body (110h) in order to removably attach with an introducer in the form of a catheter. The forming element (90) will extend through a lumen of the catheter and the catheter will be used to position the body (110h) in the coronary sinus.

Claim 14, see Figures 4h-4i and [0124] for the body comprising several wedge-shaped segments (95) with holes therethrough, together forming a tubular wall.

Claim 15, see Figure 4h for a substantially non-compressible first side.

Claims 16 and 17, see Figure 4h for a plurality of voids along the second side in the form of slots extending transverse to the longitudinal axis and permitting axial shortening on the second side (Figure 4i).

Art Unit: 3738

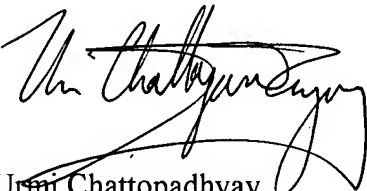
Claims 18 and 19, see Figure 4h for required number of slots.

Claims 20 and 21, see [0124] for the forming element (90) being an axially movable pull wire.

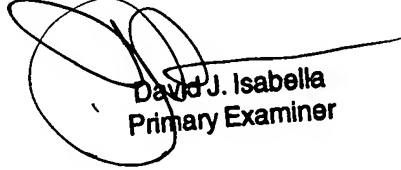
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay



David J. Isabella  
Primary Examiner

Art Unit 3738